

### **REMARKS**

This paper is filed in response to the Office Action that issued on December 15, 2008. Claims 1-5, 9-20, 22, and 23 were pending in the Present Application, and each pending claim was rejected under 35 U.S.C. § 102(e). By this paper, claim 15 is cancelled without prejudice or disclaimer, and claims 1, 9, 12, 14, 19, and 20 are amended. The Applicants respectfully submit that no new matter has been added by the claim amendments and that support for the amendments can be found in the Application as originally filed. Reconsideration of the Present Application is respectfully requested.

#### **Claim Rejections – 35 U.S.C. § 102**

Claims 1-5, 9-20, 22, and 23 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent No. 5,779,679 to Shaw (hereinafter “Shaw”). The Applicants respectfully disagree with this rejection. However, in order to expedite prosecution of the Application, claim 1 has been amended.

#### **Claim 1**

The Applicants respectfully submit that Shaw does not disclose every element set forth in amended claim 1, and thus this reference cannot anticipate claim 1. For example, amended claim 1 recites, *inter alia*,

a flange projecting outwardly from the needle hub at a position forward of the actuator; and

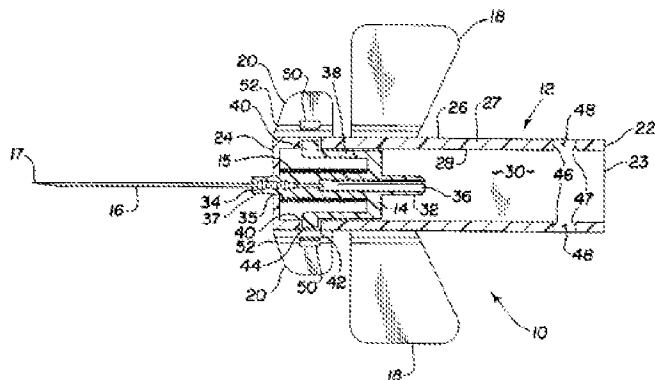
a lip projecting radially inwardly from the wall of the housing so as to define a contracted opening,

wherein the flange of the needle hub is larger in diameter than the opening defined by the lip of the housing such that a rearward edge of the flange can contact the lip,

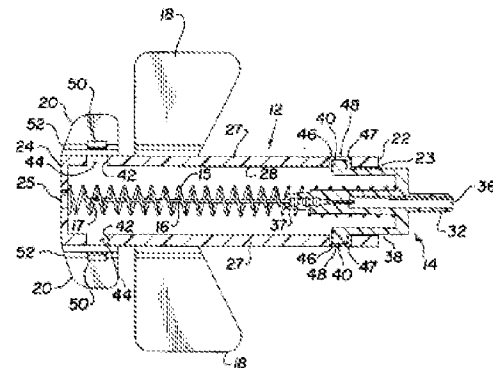
wherein, when the needle hub is transitioned from the forward position to the rearward position, the lip of the housing displaces the actuator radially inwardly such that the actuator passes rearwardly beyond the lip, and

wherein, when the needle hub is in the rearward position, the forward stop of the actuator cooperates with a rearward surface of the lip of the housing to prevent forward movement of the needle hub relative to the housing, and the lip cooperates with the flange of the needle hub to impede rearward axial movement of the needle hub beyond the rearward position.

In contrast to the foregoing, Shaw discloses a winged IV set 10 that includes a device body 12 and a needle holder 14, as depicted in Fig. 1 (reproduced below). The device body includes openings 44, 48. The needle holder 14 includes two opposing arms 38, each of which terminates in a lug 40 that is used to position and maintain the needle holder 14 in either an extended position or a retracted position. When the needle holder 14 is in the extended position, the lugs 40 are within the openings 44 of the device body 12. As shown in Fig. 2 (reproduced below), when the needle holder is in the retracted position, the lugs 40 are within the openings 48 of the device body 12.



**Fig. 1 of Shaw**



**Fig. 2 of Shaw**

As can be seen in each of Figs. 1 and 2, an inner surface 28 of a wall 27 of the device body 12 includes no lip projecting radially inwardly from the wall 27 so as to define a contracted opening at any position rearward of the openings 44. Rather, the device body 12 includes openings 48 that project outwardly from the inner surface 28. Accordingly, Shaw discloses that

[a]s needle holder 14 is sliding backwards towards back end 22 of body 12, lugs 40 will slide along inner surface 28 of body 12 as opposing arms 38 attempt to spring back from an unlocked position to their relaxed position. As needle holder 14 moves towards back end 22 of body 12, lugs 40 will slip into openings 48 and be contained between opposing pairs of shoulders 46 and 47.

Shaw, column 6, lines 9-16.

Although Shaw indicates that alternative embodiments of the winged IV set 10 “may rely on a lip or constriction in opening 23 of back end 22 [of the device body 12] to retain needle holder 14 instead of openings 48,” there is no indication that the lugs 40 would be allowed to pass rearwardly beyond such a lip or constriction. *Id.* at column 6,

lines 37-40. Indeed, allowing movement of the lugs 40 beyond such a lip or constriction of the device body 12 would permit the needle holder 14 to be completely removed from the housing. This would change the principle of operation of the winged IV set 10 and would thereby frustrate the fundamental purpose of Shaw, which is to provide for the retraction of the needle 17 so as to “significantly decrease the possibility of inadvertent needle sticks.” *Id.* at column 1, lines 7-8. The Applicants therefore respectfully submit that it would not be obvious to one of ordinary skill in the art to modify the teachings of Shaw to arrive at the limitations recited in claim 1. See M.P.E.P. § 2143.01 (VI).

Moreover, amended claim 1 recites that a needle hub comprises “a flange projecting outwardly from the needle hub at a position forward of the actuator,” and recites that a lip of the housing “cooperates with the flange of the needle hub to impede rearward axial movement of the needle hub beyond the rearward position.” No such structure is disclosed in Shaw.

An arrangement such as that recited in amended claim 1 can, in some instances, permit for a device that is readily assembled and that is difficult to disassemble. For example, for some embodiments of a medical device having a needle hub with a flange and having a housing with a lip, the flange can be resiliently compressed by the lip as the needle hub is force fitted into the housing. See Specification as filed, page 14, paragraph 2. For such embodiments, after the flange is displaced forward of the lip, it resiliently rebounds radially outward so that it is larger in diameter than a contracted opening formed by the lip. See *id.* In further embodiments, the needle hub can

thereafter be retained in a retracted-needle position via engagement of the flange with the lip. See *id.*, page 14, paragraph 1. Other flange and lip configurations and other assembly methods are also possible, such as, for example, those recited in paragraph 2 of page 14 of the Specification as filed.

For at least the foregoing reasons, the Applicants respectfully submit that amended claim 1 is patentable over Shaw. It is therefore respectfully requested that the rejection of claim 1 under 35 U.S.C. § 102(e) be withdrawn and that this claim be passed to allowance.

Claims 2-5, 9-20, 22, and 23

Each of claims 2-5 and 9-20, 22, and 23 stands rejected under 35 U.S.C. § 102(e) as being anticipated by Shaw. Claim 15 has been cancelled, thereby mooted the rejection of this claim. Because each of claims 2-5, 9-20, 22, and 23 includes all of the limitations of claim 1, Shaw fails to anticipate each of these claims for at least the reasons discussed above with respect to claim 1. Therefore, the Applicants respectfully request that the rejection of claims 2-5, 9-20, 22, and 23 under 35 U.S.C. § 102(e) be removed and that these claims be passed to allowance.

### **CONCLUSION**

In view of the foregoing amendments and remarks, the Applicants submit that the Application is condition for allowance and a Notice of Allowance is respectfully requested. Should questions exist after consideration of the foregoing, the Office is kindly requested to contact the Applicants' attorney at the address or telephone number given herein.

Dated this 16th day of March, 2009.

Respectfully submitted,

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